

PROCEDURES FOR ENCODING TOXICITY DATA PUBLISHED IN THE OPEN
LITERATURE FOR USE IN ECOLOGICAL RISK ASSESSMENTS

EFED Encoding and Data Entry

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Mid-Continent Ecology Division (MED)
Duluth, Minnesota

By

Computer Sciences Corporation
Duluth, Minnesota 55802
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Unify EFED Data Entry

Introduction

Encoding of data for EFED chemical reports is conducted through the Unify Toxicity application. From 2001 to October of 2011, encoding was completed via the Lite Eval Data entry system (See archived documentation Lite Eval Data entry). The primary coding of data fields is similar to ECOTOX coding. Differences in coding of data fields are outlined in this document.

Reviewers coding for EFED chemical reports, formerly using the LITE Eval system should be familiar with the *“Interim Guide of the Evaluation Criteria for Ecological Toxicity Data in the Open Literature. Phase I and II. Procedures for Identifying, Selecting and Acquiring Toxicity Data Published in the Open Literature For Use in Ecological Risk Assessments. Office of Pesticide Programs, U.S. Environmental Protection Agency”* (will be referred to in this document as Interim Guide) (http://neptune.ecodev.csc.com/intranet/sop_list/) prior to entering data into the Unify Toxicity data entry system.

After a paper has passed all criteria set forth in the Interim Guide, it is encoded into the Unify Toxicity data entry system. Reviewers code EFED endpoints for chemicals prioritized on the EFED Schedule, this includes all species reported in the paper. The following standard operating procedure document includes procedures for entering and quality assurance of data into the Unify Toxicity system for fields output in the “EFED Full Summary Report”. There are two additional LITE Eval standard operating procedure documents: “EFED Chemical Literature Acquisition and Skimming” and EFED Chemical Reports (both located at http://neptune.ecodev.csc.com/intranet/sop_list/). The EFED Chemical Literature Acquisition SOP describes procedures for chemical verification, literature searching and skimming and the EFED Chemical Reports SOP documents report set-up, final QA and creation of report and ProCite files.

The codes from the *ECOTOX Standard Operating Procedure - ECOTOX Code Appendix* (located at: http://neptune.ecodev.csc.com/intranet/sop_list/) are used in the Unify Toxicity data entry system, and will be referred to in this document as the ECOTOX Code Appendix.

This SOP addresses each of data fields specific to the EFED reports formerly coded into the LITE EVAL system in the order it appears on the Unify Toxicity screens. Fields noted by “(EFED)” after the field name are downloaded specifically by EFED reports. All fields are specific to the ECOTOX database and additional Unify data fields are also encoded in the Unify system at the time of EFED coding.

General Coding Guidelines

- When conflicting information is given in the paper, such as when tables and text show differing data, the text data is reported. A note is placed in the general comments field regarding the discrepancy.

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- In terrestrial field studies when a field is pre-treated with chemicals (herbicides, insecticides, fungicides) prior to the test chemicals of concern, the tests are not considered mixtures if the control fields were also pre-treated with the same chemicals. In these cases the test chemicals can be coded. If the control fields are not pre-treated in the same manner, the paper is rejected as a Mixture. If the chemicals are applied at the same time, this IS considered a mixture.
- Formulated or technical grade chemicals that report other chemicals as impurities are not considered mixtures.
- Species exposed to more than one chemical during an exposure period are not necessarily considered mixtures. In some cases, the first chemical applied is used to treat a deficiency, disease, parasite, etc. to ensure healthier test organisms or may be used to induce a biological response prior to a chemical exposure. When such a treatment is described by the authors, encode the beneficial or inducing treatment as an experimental design comment and encode the toxic effects of the chemical of concern.
- For *in situ* exposures where the exposure is by default an exposure to a chemical mixture; code residue effects or endpoints (BCF) only. No other effects or endpoints are strictly attributable to a single chemical in the same way as a residue concentration. Data for chemicals in the mixture with reported water concentrations and residue effects should be coded. The only situation in which a mixture exposure can be coded is when an *in situ* field study is conducted. The test organisms must be transplanted from a clean source and caged in the polluted source. The duration and concentration must be provided. When the author provides only the species age for the duration, it is unacceptable to code.
- To ensure accuracy in transcribing data values, all numbers between zero and one should be reported with a zero preceding the decimal point (e.g., 0.5 not .5). Periods are only used to represent a decimal point, never an abbreviation.
- To ensure consistency as well as accuracy, report the significant figures as the author reports them. Do not add or round off numbers. Report only the actual values, do not code variance information (e.g. +/-).
- When coding numbers do not use commas. They can be mistaken for decimal points or numbers.
- To make the QA process faster, reviewers should underline text in the paper that was used in the coding (i.e. purity, organism information, water parameters, exposure information, application frequency, etc.). The reviewer should also write the test numbers (1, 2, 3, etc.) in the paper next to the endpoints chosen. The test number written next to the endpoint chosen in the paper will correspond with the test number entered into Unify.

Publication Reference Number, Author, Year (EFED)

The Reference Number (Ref #) is the unique number which identifies a particular publication. This number, assigned by the data entry program, provides the link between the data entered and the original publication. The author(s) and publication year are also linked to the reference number. Use the Search References screen in Unify to locate the paper to be reviewed. Select 'Review' to begin encoding data.

Test Number

Each unique record is assigned a test number by the Unify Toxicity entry system. New records are required for each chemical, chemical formulation, species, cultivar, strain, exposure type, experimental design parameter (i.e. different temperatures, methods, salinity, etc.), and any other parameter that will influence a test scenario sufficiently to warrant an independent record. When replicates are used *and* the results are reported separately for each replicate, code each replicate as a separate test. Mean results are not coded if individual results are reported. It is also helpful for QA to write the test number in the papers next the corresponding endpoint chosen.

Unify Chemical Information TabCAS Registry Number (EFED)

The Chemical Abstracts Service Registry Number of the toxicant is populated in the CAS NUMBER field. The CAS Number is a standardized identification number and name for each chemical recorded in the database and is used for consistency. The CAS number is assigned by selecting the chemical name populated from the skim. If the chemical name is not in the Unify Chemical module, send an email with the chemical name, ECODEF #, and project name/WO to the chemical verification staff. Retain the paper until verification is complete, chemical verification staff may need the paper to complete verification. They will determine if the chemical meets the criteria for entry into the Unify Chemical module, and will add chemicals that meet the standards. The chemical verification process for EFED is outlined in the EFED Literature Acquisition and Skimming SOP (http://neptune.ecodev.csc.com/intranet/sop_list/).

If the chemical cannot be verified the chemical(s) are archived by the following :

If there are other test chemicals, in addition to the Archived chemical(s) in the publication put the archived chemical name(s) into the Other Effects field individually if $n \leq 5$ chemicals. If more than five chemicals are unverified, " n' other chemicals tested" will be put into the Other Effects field. This statement may be modified to include the chemical type if noted in the paper, e.g., "6 surfactants and 4 emulsifiers tested." Also list the same information in the note field on the front of the publication. Attach a copy of the response to the paper.

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If the unverified chemical is the only chemical tested in the paper the chemical verification staff will process the paper.

Chemical Name (EFED)

The Chemical Name is selected from the list of chemicals skimmed to the paper. Once the chemical is selected, CAS Number data field and automatically populated.

Chemical Grade

Record relevant chemical grade information in the Chemical Grade field by choosing a grade from the dropdown menu (refer to ECOTOX Appendix B). Leave the field set to the default of Not Reported if the author does not report chemical grade information.

% Purity (EFED)

The percent purity reported by the author is entered. If the purity is not reported ('NR') in the paper, the EFED report generator assumes it to be 100% for calculations. If a ranged purity is reported enter the range of purity, the lowest value entered is used for the EFED report purity adjusted report fields.

Chemical Formulation

Record the chemical formulation code for the chemical reported by choosing a formulation from the dropdown menu (refer to ECOTOX Appendix C). If there is more than one formulation code enter the code most closely related to the chemical purity, and enter the rest in the CHEMICAL COMMENTS field.

The chemical formulation is only coded when explicitly identified by the authors as the form (e.g., commercial) or when presented in a standard format (e.g., 25EC). Leave the field set to the default of Not Reported if the author does not report chemical formulation information.

Chemical Radiolabel

If a radiolabeled chemical is tested, record the isotope, according to the ECOTOX Appendix D codes, in the Radio Label field. When both radiolabeled and unlabelled test chemicals are used in a test, report the radiolabel isotope and code "labeled and unlabeled" in the Chemical Comments field. Leave the field set to the default of Not Reported if the author does not report chemical radiolabel information.

Chemical Comments (EFED)

In EFED reports, all text in this field is automatically transferred to the Comments field

during the report download.

Use this field to report any additional information about the chemical not reported in the other chemical fields.

Carrier CAS Number and Carrier Name

If a solvent carrier is used in the test, report the chemical in the Chemical Carrier field. The chemical name is typed into the Carrier Name field and the appropriate chemical is chosen from the pop-up box that appears. Alternatively, the CAS number of the carrier can be searched and added to the Carrier CAS number field, allowing the Carrier Name to be automatically populated from the Unify Chemical module.

Occasionally two or more separate carriers or solvents are used. The carrier/solvent with the highest concentration should be reported in this field. Additional carriers are reported in the additional carrier data fields. If the publication reports the ratio, include this information in the Chemical Comments field. Buffers used to control the pH of the test are not coded. Acids or bases that are added to change the pH of a solution in order to enable a metal to stay in solution are not coded. Dietary feed content is not coded. If an author states that all solvent was evaporated prior to the study or if a column coating procedure is described, the solvent is assumed to not be incorporated into the study. In this case, the Chemical Carrier field should be left blank and enter "'X' Solvent evaporated" in the test chemical characteristics, e.g. "acetone solvent evaporated". Water should not be coded as a solvent. Information in this field will be transferred into the Chemical Comments during the EFED Report download process.

Unify Species Information Tab

Species Number/ Phylum/Class/ Order/ Family/ Scientific/Common Name (EFED)

The test organism is identified by the current scientific name as verified in the taxonomic literature. Each unique test organism is assigned a species number which is stored in the Unify Species module (<http://www.epa.gov/ecotox/-> ECOTOX Species index). Select the species from the list of species skimmed to the paper. The species number will automatically be populated. If the species is not verified in the Unify Species module, send an email to the verification for species verification. For each species number, the verified name, taxonomic hierarchy, nomenclature history, and verification sources are kept on file for quality assurance documentation.

Information as to whether a species is a plant or animal and its Phylum, Class, Order, Family, Genus, Species, and Common Name is linked to the CRITTERS database. This information is automatically entered in the Unify Toxicity data entry system when a species is selected. If a phylum name is not available, the kingdom will appear in the phylum field. "Plankton" and "Aquatic Community" are not coded as EFED requires a kingdom be chosen. If a kingdom cannot be determined from the paper, the record cannot be coded.

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Additional notes on species coding issues:

Generally, when coding effects in EFED, the data are reported for each individual species, gender, and cultivar. Different lifestages of the same species are also reported separately. For example, if there are two experiments: one that exposes eggs and one that exposes newly hatched chicks, both experiments would be coded. However, if there is only one experiment that chemically exposes eggs and there are endpoints at the egg and chick stages, only the lifestage with the most sensitive endpoint is coded. Field studies may report results for a target community (e.g., beneficial and non-beneficial insects) or for an entire enclosed ecosystem (e.g. system-level primary productivity or respiration). Assign a community to the most specific taxonomic level possible (e. g. "earthworms" would be classified as "Oligochaeta," "weedy plant species" would be classified as "Magnoliophyta.")

Fill in the author reported initial Lifestage/size, Age, and Sex fields, or leave blank if information is not reported. See Appendix F of the ECOTOX Code Appendix for Lifestage abbreviations.

Habitat (EFED)

Select the habitat from the dropdown menu in which the test was performed (aquatic or terrestrial). Select Terrestrial from the habitat menu for terrestrial plants tested in hydroponic solutions. Note that some organisms may be tested in aquatic habitats during early lifestages and terrestrial habitats as adults (i.e. insects, amphibians, etc.).

Organism Lifestage (EFED)

Report the specific lifestage for the test organism at the beginning of exposure, as reported in the paper. Record as 'NR' if the information is not reported in the publication.

Organism Age (EFED)

Report the age and age unit for each test organism at beginning of exposure, as reported in the paper. The age may be a development stage if no specific time is reported. For example: The author reports that 4th instar larvae were used in the study. The following is coded:

Lifestage: LV Age: 4 Age Unit: inst

Record as 'NR' if the information is not reported in the publication.

Organism Initial Weight

The initial body weight of the organism is reported as noted by the author. If a range of weight is given for the organisms, report the range. Report the treatment group weight, if weights are given for both a treatment group and a control group.

If the author does not report body weight then enter NR in the body weight field. In generational studies, when given the choice between reporting the body weight for the dosed mother or the offspring, the mother's body weight should be coded.

Organism Comments (EFED)

In EFED reports, all text in this field is automatically transferred to the Comments field during the report download.

Include any organism information not reported in the other organism fields (e.g. length, cultivar/variety name, strain, etc.)

Unify Test Information Tab

Application Frequency

Report the frequency of the dose application in the Application Frequency data field. For example, if the exposure type is flow-through or continuous flow in aquatic studies, code "NA" as the frequency and "CON" as the unit in the Application Frequency field. If the exposure type for an aquatic study is static, code "1" as the frequency and "X" as the unit in the Application Frequency field. If an application frequency is not reported, record NR. See Appendix K of the ECOTOX Coding Appendix for Application Frequency codes. If an Application frequency unit is missing from the dropdown menu, send an email to the code verification person stating the new unit needed and the EcoReference number of the paper it came from.

Note: The "X" in an application frequency unit represents the number that is written prior to the code.

Examples:

The author reports that the water was renewed every 48 hours. Code:
APP FREQ: 48 E X H

The author reports that the chemical was applied 3 times a month. Code:
APP FREQ: 3 X per MO

The author reports that the chemical was applied as a pulse dose of 3 hours every day.
Code:
APP FREQ: 3 H per D

Control

Select a control from the dropdown menu that best fits the methods. If multiple controls are used (e.g. concurrent and baseline) enter all of the Control types used for the specific test (e.g. C and B). EFED LiteEval coding requires a control, so the codes for Insufficient,

Unsatisfactory, or No Controls cannot be selected. See Appendix M of the ECOTOX Coding Appendix for control types.

Conc Type (EFED)

This is the first of two Conc Type fields on the Unify data entry screen. This field refers to the concentration type of the Concentration Values tested. The concentrations tested were entered into the Conc Value field described in the paragraph above.

The other Conc Type field on the Unify data entry screen refers to the concentration type of the of the Endpoint concentration and is discussed later. These two Conc Type fields may report different codes (e.g. the author reports the different chemical concentrations tested in experimental fish tanks as nominal, but reports LD50 values from measured chemical concentrations taken during the study). The same requirements are used for coding both Conc Type fields.

The three forms of toxicants evaluated in LiteEval Coding are organic compounds, metals and inorganic non-metals. Each form is identified as a concentration type code using the single letter abbreviation (A, F, T, D, U, L, and NR).

Organic compounds are defined by the pesticidal terms, formulation (F) and active ingredient (A). Select from the dropdown list if the chemical concentration is based on active ingredient (A) or formulation (F). Concentration Type is also linked to the Chemical Analysis Method field (see discussion below on Active Ingredient). If the chemical concentration is reported as measured; the concentration type is coded as A. If the chemical concentration is reported as nominal, the concentration type is coded as F. If the authors do not clearly state whether or not the chemical concentration was measured or whether the reported concentrations are based on formulated product vs. active ingredient, select the code NR.

Metals are defined by the concentration types, total (T), dissolved (D), and labile/free (L); while ammonia or hydrogen sulfide compounds may have total concentrations (T) and/or un-ionized (U) concentrations. Organometals are coded as total (T) concentrations.

Concentration Types and Definitions :

Organic:

FORMULATION (F): Way in which basic pesticide (toxicant) is prepared for practical use (Ware, 1978). Generally reserved for commercial preparation prior to actual use and does not include the final dilution (Insect-Pest Management and Control, 1971) (e.g.; Baythroid, 2,4-D). Also included in this category are organic compounds with no pesticidal activity (e.g.; PCB, dioxin).

ACTIVE INGREDIENT (A): Chemical substance in a product that is responsible for the pesticidal (toxic) effect (Ware, 1978). Reported as "A" when the author refers to the concentration as active ingredient, active principle, active substance (A.S.), acid equivalent or various grades of reagents (i.e., Analytical, Reagent or Technical, see ECOTOX Appendix for complete listing). When coding,

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a value in the publication may be reported as "AI kg/ha" , "AE kg/ha" or "kg AI/ha"; this type of value is reported as 'A =' for CONC TYPE.

If author reports both Formulation (F) and Active Ingredient (A) concentrations the Active Ingredient (A) concentrations are coded.

Note: Information reported in the PURITY field does not necessarily determine whether concentration is A or F. In addition to the description above, using "A" as the concentration type occurs in situations such as the following:

- 1) Author states concentration of pesticide as "AI".
- 2) Author states %AI (PURITY) and reports measured concentration.
- 3) Author states measured concentration of a pesticide.

Metal/Organometals:

TOTAL (T): The concentration of metals determined on an unfiltered sample after vigorous digestion, or the sum of the concentrations of metals in both dissolved and suspended fractions (APHA et.al. 1992). Heavy metals and single elements (e.g. Na, Cl, Br) are coded as T.

DISSOLVED (D): Those constituents of an unacidified sample that pass through a 0.45 um membrane filter (e.g. soluble metal) (APHA et.al. 1992).

LABILE (L): The labile or free ion metal concentration determined by various analytical methods. When coding, the specific labile forms or complexes are not differentiated.

Inorganic non-metals:

Concentrations of ammonia and hydrogen sulfide are reported in the literature in either the total or unionized form. Code the form as specified by the author. Ammonia may be reported as a variety of different forms, eg., NH_3 , NH_4^+ , $\text{NH}_3\text{-N}$, NH_4OH , or NH_4Cl . (US EPA 1979) The author must state whether the form is **Total** or **Unionized**; **T** is the default for ammonia and hydrogen sulfide papers that do not state whether total or unionized concentrations are reported.

TOTAL (T): The dissociated, charged form of nitrogen or hydrogen related chemicals. This can take on numerous forms, e.g.; ammonium (NH_4^+), nitrite (NO_2^-), etc. (Rand and Petrocelli, 1985). **T** is the default for publications that do not state whether Total or Unionized concentrations are reported.

UN-IONIZED (U): The undissociated, uncharged form of ammonia or hydrogen sulfide. The ammonia molecule, NH_3 , is the unionized form. (In aqueous solution, ammonia assumes equilibrium between NH_3 and NH_4^+ .) The NH_3 is the toxic entity of the ammonia compound (Rand and Petrocelli, 1985).

Test Location (EFED)

Select the location or setting in which the experiment was conducted from Test Location dropdown menu. For example, a natural field study (FieldN) is an experiment conducted outdoors in a natural setting. The test organisms are sampled in the wild, e.g. population counts. Outdoor studies conducted in a simulated environment are coded as an artificial

field study (FieldA). Artificial field studies include organisms isolated from their natural environment via an enclosure of some type, e.g. cages or fencing. If the publication does not provide enough information to distinguish between FieldA and FieldN, then use the code FieldU to indicate that the field test type is unknown. Laboratory tests (LAB) are conducted indoors under controlled laboratory conditions. The location must be reported; NR cannot be chosen. See Appendix H of the ECOTOX Coding Appendix for Test Location abbreviations.

Exposure Type (EFED)

For the Unify database, the term ‘exposure’ refers to the mechanism by which the toxicant was applied. Organisms are typically exposed to toxicants through diet, injection, topical or environmental routes. The Exposure Type coded should be as specific as what the author reports. For example, if the author reports a subcutaneous injection exposure, “subcutaneous” should be chosen from the dropdown menu, not “injection, unspecified”. For aquatic organisms the exposure type is reported as the treatment system, such as static, renewal, or flow-through. The eight Exposure Types specific to Aquatic studies (static, renewal, flow-through, pulse, leachate, tidal, lotic, and lentic) should not be chosen for records with terrestrial organisms. Select the appropriate exposure type from the dropdown menu. The codes can also be found in Appendix J of the ECOTOX Code Appendix.

On occasion, an exposure may be through multiple routes (e.g., such as topical and oral). Multiple exposure route coding is applicable when the organism is exposed through two *independent* applications, for example, a contaminated diet *and* a topical application for animals or contaminated soil *and* leaf spray for plants. In this scenario, ‘MU’ would be entered into the Exposure Type data field and a remark noting the types of exposure is coded in the comments field.

Media Type (EFED)

Select the type of exposure media from the dropdown menu, (e.g., natural or artificial soil, fresh water, filter paper), in the Media Type field. Select “No substrate” for the species that do not have a media type (e.g. rodents, mammals). Report as 'NR' if you cannot determine the exposure media from the paper. If “Media Mixture (with comment)” is chosen, a description of the media must be placed in the Experimental Design field. The two Media Types specific to Aquatic studies (freshwater and saltwater) cannot be chosen for records with terrestrial habitats.

For aquatic habitat studies, only freshwater (FW), saltwater (SW), or not reported (NR) can be selected as Media Types. Freshwater (FW) tests include 1) laboratory tests conducted in freshwater, reconstituted water, distilled water, or tap water or 2) field tests where the organism habitat is exclusively freshwater. If a salinity value of <4 0/00 is reported and the paper does not specify whether it is fresh or saltwater, it will be coded as a freshwater test. Saltwater (SW) tests include 1) laboratory tests conducted in natural or artificial seawater,

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brackish water, or estuarine water or 2) field tests where the organism habitat is exclusively saline. If a determination cannot be made regarding the use of either freshwater or saltwater, an NR (not reported) is recorded. See Appendix L of the ECOTOX Coding Appendix for Media Type codes.

Number of Concentrations/Conc Values/Conc Units (EFED)

Provide the number of concentrations tested, the concentrations, and the units in these fields. If a concentration range is provided, type "to" between the numbers (e.g. 1.5 to 10, not 1.5-10). Make a selection from the Conc Units dropdown menu. If the author reports that the concentration is based on active ingredient or acid equivalent choose the unit preceded by AI or ae from the dropdown menu (e.g. AI mg/kg or ae mg/kg). If a concentration unit is missing from the dropdown menu, send an email to the code verification person stating the new unit needed and the EcoReference number of the paper it came from.

If the Concentration values are not reported by the author, code NR for Number of Concentrations, the concentration type of the reported endpoint value, NA in the concentration value field and the concentration unit of the reported endpoint value.

Example: A LC50 value of 10 AI ug/L is reported, but the author does not report the doses tested:

Code:

No. Conc: NR Conc Type: A Conc values: NA Conc Unit: AI ug/L

If the author reports concentrations as exponential numbers expand the concentrations to decimal form. If the values exceed the total field length they can be reported as an exponential number (e.g., 1×10^8 ; often reported as 10^8) is coded as E+n or E-n (e.g., 1 E+8).

Occasionally an author will report a concentration as a % or fraction of an LC50 value or application rate; e.g., "sublethal concentration used was 10% of the 96-h LC50", "1/10, 1/15 and 1/20 of the LC50", or "chemical was applied at 0.25X, 0.5X, 1X, 2X, 4X of the recommended rate." Such concentrations may be recalculated and used as the concentration tested if the base concentration is provided in the publication. Flag the recalculation in the paper so that the calculation may be QAed and document the recalculation in the margin or on a blank page of the publication. Remark "Recalculated" in the general comments (e.g. DOSES/recalculated//).

Experimental Design (EFED)

In EFED reports, all text in this field is transferred to the Comments field

This field is used to explain aspects of a paper's methods that assist viewers in

understanding the coding (i.e. prior treatment of fields with herbicides/fungicides, inducing treatments, number of replicates, treatment protocols, multiple exposure routes, dosing regime, and any additional study parameters not coded in another field).

For field tests, report the exposure system dimensions (cage or enclosure size) and type of artificial substrate (if used).

If an organism is pre-exposed to another chemical and this is the only information that can be coded, the chemical that is associated with the observed effect is coded and “preexposure with X” is noted in the Experimental Design field. On occasion, an author will note that organisms were sampled during the course of a study for analysis. Note “Sub-sampled” in the Experimental Design field.

Example: Author tests organisms for residue and mortality over a 30 day study. At day 5 and 10, several organisms are pulled from the study for residue analysis. At the end of the test (30d) the mortality is reported. Note “Sub-sampled” in the Experimental Design field of the records directly affected, since these sub-sampled organisms may or may not be included in the final calculation for mortality.

When coding field or lab exposure publications, additional related coding parameters that do not get coded in the Habitat or Substrate fields, are added to the Experimental Design field.

Example: suspended mesh bags

Unify Habitat Information

Habitat Code (aquatic field studies only)

Codes based on the Cowardin system code (see ECOTOX Appendix X) are used to describe the habitat. For Aquatic Field studies select either Lacustrine, Estuarine, Marine, Palustrine, or Riverine from the dropdown menu.

Geographic Code (aquatic and terrestrial field studies only)

This field will contain the state, province or country name of the test site along with the Geo code. Select the appropriate location from the dropdown menu. If the test site is not reported, the field is left empty. (ECOTOX Appendix BB contains a listing of country, region, province names and associated Geo code.)

Substrate (aquatic field studies only)

The bottom substrate in Aquatic field studies is chosen from the dropdown menu (e.g. clay, gravel, mud). The Substrate codes are also listed in ECOTOX Appendix Y. If there are no applicable codes, record as the author states in the literature. If a substrate is not reported

the field is left empty. A mixture of sediment types is coded as "Mixture" and text is included identifying the most prevalent soil type(s) in the mixture in the Experimental Design field.

Application Date (aquatic and terrestrial field studies only)

The application date is the time of initial exposure. The format is mm-dd-yyyy, e.g. 12-01-1993. If one or more parts of the date is not reported, code the letter of the date that is missing (e.g. 12-dd-1993, mm-dd-1993, 06-15-yyyy). If more than one initial date is reported (e.g. more than one pond exposed), record the additional dates in the General Comments. If one pond is exposed multiple times, only report the first application date and note #x in frequency. If the application date is not reported, the field is left empty.

Water Depth (aquatic field studies only)

Water depth value and unit are coded for the study site, as reported by the author. The field is left empty if the author does not report the water depth at the study site. If the author only reports the water depth of the entire system or the depth at which experimental units (i.e., cages) are suspended, the field is left blank, and depth information is included in the Experimental Design field. (See ECOTOX Appendix Z for valid unit codes)

Unify Results Screen

Duration/ Duration Unit (EFED)

The exposure duration is a mandatory field for inclusion in the Unify database. In cases where the observation time is the only duration reported, it is assumed that the exposure duration is equivalent to the observation time. If the exposure duration is not reported, the paper is rejected. The period of time recorded in the DURATION data field is the time of actual exposure to the chemical. In some cases a biological time is used, such as an exposure time reported as "until hatch", "growing season" or "after the nth egg has been laid". 'NA' will be coded as the duration value for all biological time durations (e.g. Duration: NA, Duration Unit: hv; corresponds to an at harvest duration). However, references to time such as "observed at end of the study period" are not coded; such papers are rejected as having no exposure duration.

For injection, diet, topical and environmental exposures where the actual exposure is dependent on biological and environmental conditions, the exposure time is recorded as equivalent to the study time (even if the study spans multiple generations). This assumption is made to ensure consistency in data representation; it is not necessarily a true reflection of the exposure time.

If a set of ranged values are presented for a duration value, report only a single value. For a ranged duration the lowest duration is coded for all endpoints except for NOEC, NOAEL and NR-ZERO for which the longest duration is encoded. In these cases, a comment is made reporting the ranged values.

EFED: LITE EVAL Data Entry

Ex 1. The author reports the LC50 from 24-48 hours.

Duration: 24 h

Comment: ExpDur/24-48 hours reported//

Ex 2. The author reports the NOEC from 15 - 18 days.

Duration: 18 d

Comment: ExpDur/15-18 days reported//

Duration Comment (EFED)

In EFED reports, all text in this field is automatically transferred to the Comments field during the report download.

Record any information necessary to understand the duration of exposure (e.g. exposure times based on lifestages, complex exposure explanations, etc.)

Endpoint (EFED)

Note that Endpoint 1 and Endpoint 2 values in the EFED reports are generated from NOxx/LOxx companion endpoints contained in the Unify Toxicity data entry application. All other endpoints are contained in Endpoint 1 value.

An endpoint is a value derived from statistical analysis or calculation of a specific measurement, or series of measurements, made during the test. Endpoints may be classified as measurement endpoints or assessment endpoints. Assessment endpoints refer to environmental parameters such as population, community or ecosystem measurements, e.g., growth rates or sustainable yields. Measurement endpoints refer to specific variables that are used to evaluate the assessment endpoints, such as diversity or evenness. (Hoffman et.al. 1995; US EPA 1996)

The ECOTOX databases utilize assessment and measurement endpoints which quantitatively represent the response(s) of a given individual, population, or community to the effects of a toxic agent. Appendix T of the ECOTOX Code Appendix lists and defines endpoints used in Unify.

All author reported endpoints are coded (e.g. EC50, LC50, LC25). However, if more than one duration is reported for the same endpoint or multiple values for the same point are reported, the most sensitive value is coded, with the exception of BCF/BAF (see below for further details about BCF/BAF). If a data set is evaluated using more than one statistical analysis the endpoints are coded on separate records (e.g. 2 LC50s for same data using probit and Spearman-Kärber will be coded as two separate data records) and report statistical method in Endpoint comments. Additionally, note OEF/statistical comparison// in the General Comments field. (see OTHER EFCT section for more information).

EFED: LITE EVAL Data Entry

If within a single experiment, the authors report the same endpoint and the exact same concentration at all durations, only code the duration most relevant to the OPP SEPs taken from the July 9th, 2004 Interim Guidance (see table below) and note the other endpoints in the comments field:

EFED: LITE EVAL Data Entry

EFED SEP DURATION TABLE		
SEP Category	Test Protocol	Recommended Duration
Aquatic Animals		Typical Duration
Acute	freshwater fish	96 h
	freshwater invertebrates	48 h
	estuarine/marine fish	96 h
	estuarine/marine invertebrates	96 h
Chronic	freshwater fish	28-32 d
	freshwater invertebrates	21 d
	estuarine/marine fish	28-32 d
	estuarine/marine invertebrates	
Terrestrial Animals		
Acute Avian	LD50 (single oral dose)	14 d
	LC50 (subacute dietary)	5 d
Chronic Avian	NOEC for 21-week avian reproduction test	21 wk
Acute Mammalian	LD50 from single oral dose test	4 d
Chronic Mammalian	NOEC for 2-generation reproduction test	2 generations
Plants		
Terrestrial	EC25 values - seedling emergence (monocots/dicots)	21 d
	EC25 values - vegetative vigor (monocots/dicots)	21 d
Aquatic vascular, algae		
	EC50 for vascular plants	7 d
	EC50 for algae/nonvascular	7 d
Bees		
	contact (LD50)	24 h
	residue (RT25)	24 h

Endpoints of NOEC/LOEC are only reported as “NOEC” and “LOEC” if the author specifically reports this terminology.

If the author does not explicitly identify a NOEC/LOEC or a NOAEL/LOAEL (see Appendix T of the ECOTOX Code Appendix), NOAELs and LOAELs are determined by the reviewer by analyzing the author reported statistical analysis. The NOAEL is the highest tested concentration having no statistically significant adverse effect and the LOAEL is the lowest tested concentration having a statistically significant adverse effect. (Rand, 1995).

Reviewer Identification of the NOAEL and/or LOAEL

The Reviewer may be required to review each toxicological study and to identify No Observed Adverse Effect Level (NOAEL) and/or Lowest Observed Adverse Effect Level (LOAEL) values.

It is important to note that the NOAEL and LOAEL are endpoint specific. For example, the selected LOAEL for a growth endpoint may be 5.7 Kg/ha whereas the LOAEL for a population endpoint may be 2.3 Kg/ha. Publications or documents which report studies of interest to the regulatory community may identify both a NOAEL and a LOAEL, only a NOAEL, or only a LOAEL. Many publications, particularly those reporting basic toxicological research, do not identify NOAEL or LOAEL values. In these cases, the Reviewer must determine whether there are sufficient data available to determine NOAEL and/or LOAEL values.

The process of identifying a NOAEL and/or LOAEL begins by determining whether statistical analysis of the data was performed. This may be obvious from presentation of data in summary tables. However, the Reviewer should carefully examine the text in the methods section, text of the results section, and footnotes in data tables for information on statistical analysis and results. In cases where no statistically significant results were observed, the only indication that statistical analysis was performed may be a description provided in the methods section. If an appropriate statistical analysis has been performed, the Reviewer applies the general rules below to identify NOAEL and/or LOAEL values. The general rules for determining each LOAEL/NOAEL and their exposure durations are as follows:

- The Reviewer identifies a NOAEL when there are no statistically significant differences. The Reviewer also identifies a NOAEL where there are sporadic, statistically significant differences, but no clear dose response (e.g., a statistically significant difference is reported at a low or mid dose but not at higher doses). In this case “no clear dose response” is reported in the Endpoint Comments section. The highest concentration and longest exposure duration is coded with a NOAEL.
- There are five experimental design scenarios possible when identifying a LOAEL:

EFED: LITE EVAL Data Entry

1. If one result is reported (single concentration and single duration) and the difference at that only data point is significant, then the reviewer codes a LOAEL at that duration and concentration.
2. When there are multiple durations reported for one concentration and the organisms are dosed one time only (acute exposure), the first significant duration is chosen as the LOAEL, even if the data turns non-significant at later durations (See Example A). If the endpoints then go non-significant and again back to significant later (i.e. no statistical trend), a NOAEL is coded at the last duration and “no clear dose response” reported in the Endpoint Comments (See Example B).

Example A – Acute Exposure – Multiple Durations/One Concentration

	Day 1	Day 2	Day 3	Day 4	Day 5	NOAEL/LOAEL
10 mg/kg	no	no	sig	sig	no	Day 3 LOAEL 10mg/kg

Example B – Acute Exposure – Multiple Durations/One Concentration

	Day 1	Day 2	Day 3	Day 4	Day 5	NOAEL/LOAEL
10 mg/kg	no	sig	no	sig	no	Day 5 NOAEL 10mg/kg No clear dose response

3. When there are multiple durations reported for the same concentration and the animals are dosed continuously, the LOAEL is only coded when the trend goes from non-significant to significant and does not change back at a later duration (See Example C). In this case the LOAEL is coded at the first significant duration. If the data changes back to non-significant at later durations, a NOAEL is coded at the last duration and “no clear dose response” reported in the Endpoint Comments (See Example D).

Example C – Continuous Exposure – Multiple Durations/One Concentration

	Day 1	Day 2	Day 3	Day 4	Day 5	NOAEL/LOAEL
10 mg/kg/d	No	no	sig	sig	sig	Day 3 LOAEL 10mg/kg/d

Example D – Continuous Exposure – Multiple Durations/One Concentration

	Day 1	Day 2	Day 3	Day 4	Day 5	NOAEL/LOAEL
10 mg/kg/d	No	no	sig	sig	no	Day 5 NOAEL 10mg/kg/d No clear dose response

4. When data are reported at multiple concentrations but only at a single duration, the reviewer assigns a LOAEL at the lowest, significant concentration (See Example E). Because multiple concentrations are

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reported in this case, companion NOAELs (at the largest concentration without a significant adverse effect) may be coded. When there is no clear dose response (e.g. the result is significant at a low concentration but not at a higher concentration), a NOAEL at the highest concentration is coded and “no clear dose response” is reported in the Endpoint Comments (See Example F).

Example E – One Duration/Multiple Concentrations

	Day 1	NOAEL/LOAEL
10 mg/kg/d	no	Day 1 NOAEL at 10 mg/kg/d, LOAEL at 20 mg/kg/d
20 mg/kg/d	sig	
30 mg/kg/d	sig	

Example F – One Duration/Multiple Concentrations

	Day 1	NOAEL/LOAEL
10 mg/kg/d	no	Day 1 NOAEL at 30 mg/kg/d, No clear dose response
20 mg/kg/d	sig	
30 mg/kg/d	no	

- When the paper provides results at multiple durations and multiple concentrations, the reviewer first looks at the lowest concentration. If there is a significant, adverse effect (and a clear dose response), the shortest duration is coded. If there is no adverse effect at the lowest concentration, then the reviewer proceeds to the next lowest concentration, and so on. When deciding between LOAEL endpoints at the shortest duration or lowest concentration, the lowest concentration takes precedence (See Example G)

Example G – Multiple Durations/Multiple Concentrations

	Day 1	Day 2	Day 3	LOAEL/NOAEL
10 mg/kg/d	no	no	sig	Day 3 LOAEL at 10 mg/kg/d
20 mg/kg/d	no	sig	sig	
30 mg/kg/d	sig	sig	sig	

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The following examples are provided to assist in properly assigning NOAEL and LOAEL values when multiple durations and multiple concentrations are reported and were taken from EcoSSL Guidance Documents 4-3, Standard Operating Procedures #4: Wildlife TRV literature review, data extraction and coding (<http://www.epa.gov/ecotox/ecossl/SOPs.htm>):

Example 1

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	no	no	2 week LOAEL 10
2 weeks	sig	sig	sig	
3 weeks	no	no	no	

Example 2

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	no	sig	1 week NOAEL 20; LOAEL 30
2 weeks	no	sig	no	
3 weeks	no	no	sig	

Example 3

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	sig	no	2 week NOAEL 20; LOAEL 30
2 weeks	no	no	sig	
3 weeks	no	sig	no	

Example 4

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	sig	no	no	3 week NOAEL 20; LOAEL 30
2 weeks	no	sig	no	
3 weeks	no	no	sig	

EFED: LITE EVAL Data Entry

Example 5

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	no	sig	1 week NOAEL 20; LOAEL 30
2 weeks	no	sig	no	
3 weeks	sig	no	no	

Example 6

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	no	no	3 week NOAEL 30
2 weeks	no	no	no	
3 weeks	no	no	no	

Example 7

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	sig	no	3 week NOAEL 30 (No dose response)
2 weeks	no	sig	no	
3 weeks	sig	no	no	

Example 8

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	sig	no	3 week NOAEL 30 (No dose response)
2 weeks	no	sig	no	
3 weeks	no	no	no	

Example 9

Duration\Doses	10 mg/kg/d	20 mg/kg/d	30 mg/kg/d	NOAEL/LOAEL
1 week	no	sig	no	3 week NOAEL 30 (No dose response)
2 weeks	no	sig	no	
3 weeks	no	sig	no	

- When selecting among multiple Effect Measures for the Same Effect type, the Effect Measure resulting in the lowest concentration LOAEL is coded, provided a clear dose response relationship is evident. For example, if a population abundance (POP/ABND) LOAEL of 0.50 kg/ha and (POP/BMAS) biomass LOAEL of 0.75 kg/ha were both reported, the more sensitive LOAEL of 0.50 kg/ha would be reported as the endpoint and Biomass would be recorded in the Endpoint Comment field. If both Effect Measure LOAELs are at the same concentration, then the LOAEL at the shorter duration is coded. If the LOAELs are at the same concentration and duration, the Effect Measure LOAEL with the smaller p-value is coded. If the LOAEL concentrations, durations, and p-values are all the same for multiple Effect Measures, then the reviewer chooses one LOAEL to represent the Effect Measures.

If there are multiple Effect Measures for the Same Effect Type, but they are from distinctly different experiments, each Effect Measure would be coded. For example, Exp1 has a POP/ABND endpoint, Exp2 has a POP/BMAS endpoint, and Exp3 has a POP/ABND endpoint, all three endpoints would be coded for the same paper.

- Positive/beneficial effects (e.g. increase in growth (GRO) over control, decrease in injury (INJ) over control, increase in abundance (POP) over control) that are statistically significant are coded as NOAELs and the longest duration is recorded. A remark must be placed in the Endpoint Comments field stating either “statistically significant increase over control” or “statistically significant decrease over control”, whichever is applicable.
- Companion endpoints (i.e. NOAEL/LOAEL) may be reported in the same test record if the endpoints are for the same duration, effect measurement, and test.
- When a paper contains endpoints for the same effect measurement for both drug-induced state organisms and “clean” organisms, only the endpoints using “clean” organisms should be coded. For example:

Ecoref# 84729 -- Some rats are pre-treated with deoxycorticosterone (DOCA) to determine if nicotine exacerbates the blood pressure increase in DOCA - salt hypertension. The paper reports blood pressure for clean controls, DOCA controls, nicotine-only treated rats, and rats given both DOCA and nicotine. There are stats comparing blood pressure in the clean controls to the nicotine-only treated rats, and stats comparing the DOCA control rats to the DOCA-nicotine treated rats. In this case, only the blood pressure endpoint for the nicotine-only treated rats vs. clean controls should be coded.

However, if the paper only presents drug-induced experiments, those drug-induced endpoints would be coded.

- Endpoints during recovery phases are not coded unless they are the only data reported for an effect in the paper. Recovery endpoints in aquatic papers are data taken after the transfer of organisms from treated water to clean water. The only terrestrial studies with recovery endpoints usually involve earthworms moved from treated to clean soil. Diets that are changed from treated to clean food/water,

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injections that are stopped, or environmental applications that dissipate are not considered recovery effects. If an endpoint must be coded during the recovery phase, "Recovery" is noted in the Endpoint Comments.

The occurrence of no mortality (0%) or complete mortality (100%) is treated as an endpoint. The endpoints NR-LETH and NR-ZERO will always be coded for mortality effects of 100% mortality and 0% mortality, respectively. The 100% mortality data point at the lowest concentration/ shortest duration is coded. Similarly, the 0% mortality data point at the highest concentration/ longest duration is coded.

If for a laboratory test exposure the authors report "all fish died", code as NR-LETH and 100% mortality; however, for a field exposure, unless conducted in an enclosure of some type, it is difficult to assume that truly 100% of the fish are known to be dead, therefore the field exposure report of "all fish died" is not coded. The term "nil" is defined as "naught or nothing", therefore, when used by an author, it will be assumed to mean 0% mortality and coded as NR-ZERO.

In contrast to other endpoints, the additional mortality effects are coded along with the NR-LETH and NR-ZERO endpoint data. For example:

Mortality Table 1

ug/L	24 H	48 H	72 H	96 H
1	0	0	0	0 NR-ZERO
2	5	17	30	35
3	25	40	65	90
4	100 NR-LETH	100	100	100

A) LC50s reported in publication, code:

LC50s as reported

NR-LETH: 4 ug/L at 24 hr

NR-ZERO: 1 ug/L at 96 hr

B) LC50s not reported in publication, code:

NR-LETH: 4 ug/L at 24 hr

NR-ZERO: 1 ug/L at 96 hr

Mortality Table 2

ug/L	24 H	48 H	72 H	96 H
------	------	------	------	------

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1	0	0	0 NR-ZERO	11
2	20	25	38	72
3	45	60	67	90
4	90	100 NR-LETH	100	100

A) LC50s reported in publication, code:

LC50's as reported

NR-LETH: 4 ug/L at 48 hr EFCT%: 100

NR-ZERO: 1 ug/L at 72 hr EFCT%: 0

B) LC50s not reported in publication, code:

NR-LETH: 4 ug/L at 48 hr EFCT%: 100

NR-ZERO: 1 ug/L at 72 hr EFCT%: 0

Mortality Table 3

ug/L	24 H	48 H	72 H	96 H
1	0	0	7	13
2	0	28	45	60
3	38	44	67	100
4	38	60	100	100

A) LC50s reported in publication, code LC50's as reported

B) LC50s not reported in publication, code nothing

Mortality Table 4

ug/L	24 H	48 H	72 H	96 H
1	0	0	0	0
2	0	0	7	13
3	0	28	45	60
4	38	44	67	100
5	38	60	100	100
6	100	100	100	100

A) LC50s reported in publication, code LC50's as reported

B) LC50s not reported in publication, code nothing

Trend

The observed or measured response trend as compared to the control is coded when reported or graphically displayed.

Effect Type (EFED)

Select from the dropdown menu the specific observed effect as presented in Appendix S of the ECOTOX Code Appendix. When an author reports multiple endpoints under the same Effect Type, only the most sensitive endpoint is chosen. For example, if an author reports endpoints for three different enzymes, only the enzyme with the most sensitive endpoint is coded.

Effect Measure (EFED)

Generally, “measures” or “measurements” are variables used to aid in the interpretation of the degree of response to a toxicant by an organism. Select an appropriate Effect Measurement from the dropdown menu. Codes can also be found in Appendix S of the ECOTOX Code Appendix also lists the measurements currently used for each of the effects in the Unify database. If an Effect Measurement is missing from the dropdown menu, send an email to the code verification person stating the new effect measurement needed a definition for the effect, and the EcoReference number of the paper it came from.

Response Site

A response site code is used to identify specific organ and tissue effect sites for effect measurements. For example, response sites are used for ACC, BIO, CEL, HIS, PHY, GRO, and MPH effects and associated endpoints. Select the response site from the dropdown list. If a response site is not reported or not applicable, e.g. mortality, behavioral effects, leave the field blank. See Appendix U of the ECOTOX Coding Appendix for Response Site abbreviations.

For generational studies with measurements based on the progeny (F1, F2, C1, C2, etc) use the sample number and unit field abbreviations to encode the information in the General comments. For example, to report a BCM measurement determined in the Liver of progeny, select LI in the Response Site dropdown and enter “SAMPN/NR// NUNIT/F2//” in General Comments, also enter “measured in F2 progeny” in the Endpoint comments.

Effect % Response

The Effect % Response field is used when the effect is reported as a percent change (e.g. percent of the total population or percent increase or decrease). Do not recalculate author

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reported data into percent. If the percent effect is coded from a graph, code the percent values using a qualifier, i.e. <, >, or ~. If the effect percent is not reported, the field is coded as NR. For NR-ZERO and NR-LETH endpoints, the field is coded as 0% and 100%, respectively.

Conc Type/Value/Unit (EFED)

This is the second of two Conc Type fields on the Unify data entry screen. This field refers to the concentration type of the Endpoint concentration.

The other Conc Type field on the Unify data entry screen refers to the concentration type of the initial Concentration Values tested and was discussed earlier. Refer to the first Conc Type discussion to code an appropriate type here. Again, these two Conc Type fields may report different codes (e.g. the author reports the different chemical concentrations tested in experimental fish tanks as nominal, but reports LD50 values from measured chemical concentrations taken during the study).

Report the Endpoint concentration in the same units used by the author. If the author reports that the concentration is based on active ingredient or acid equivalent choose the unit preceded by AI or ae from the dropdown menu (e.g. AI mg/kg or ae mg/kg). Do not convert any units. (See ECOTOX Appendix N for a list of concentration units). The confidence interval, fiducial limits, or range is recorded in the following format Mean(min to max) if available and greater than zero, record confidence intervals with negative values in the Endpoint Comments "Author reports confidence limit as (min to max)". If an aquatic study, the water concentration is coded in this field, except for diet studies, where the concentration in the food is coded. If a test is run with two sources of chemical, such as diet and water, code the concentration of the diet in the CONC field, the EXP TYPE field as FD and code CONC/water conc rpt// in the REMARK field. If the concentration reported from spiked sediment studies is the pore or overlying water concentration, record the concentration in the CONC field, and code CONC/pore water from spiked sediment// or CONC/overlying water from spiked sediment// in the REMARK field and ensure that the Exposure Type is 'L' (leachate). When multiple dose/concentration units are reported (e.g., ppm and mg/kg body wt), code the unit that represents the more accurate dose the organism receives (e.g., mg/kg body wt is more accurate than ppm).

BCF

The bioconcentration factor (BCF) is a unit-less value describing the degree to which a chemical can be concentrated in the tissues of an organism in the aquatic environment. At apparent equilibrium during the uptake phase of a bioconcentration test, the BCF is the concentration of a chemical in one or more tissues of the aquatic organism divided by the average exposure concentration in the water. The unit-less number is calculated by dividing the concentration of the exposure chemical found in the tissue by the concentration of the

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chemical found in the exposure water,

$$BCF = \frac{\text{g/kg chemical in organism tissue}}{\text{g/L chemical in H}_2\text{O}}$$

g/L chemical in H₂O

or it is calculated from a ratio of rate constants, if at steady state,

$$BCF = \frac{K1 (\text{uptake})}{K2 (\text{elimination})}$$

The author-reported BCF value is coded in the BCF field. If an author reports more than one type of BCF (i.e. lipid normalized, regular, or radioactive equivalents) for the same data point; code lipid normalized over regular and regular over radioactive equivalents.

Information in this field is automatically transferred into the Comments during the EFED Report download process.

When multiple concentrations, durations and/or tissues are reported with BCF or BAF values, the highest BCF or BAF value among the concentrations tested at the longest duration is coded.

e.g., BCF values are reported for three durations, four concentrations and three tissues. The highest BCF value at the longest duration is coded in the case below, the Liver BCF of 700 at 60 days and 500 ug/l is coded, with 700 being recorded in the BCF Field. The Endpoint Comment would be: Intestine and Kidney BCFs at 40, 50, and 60 days and additional concentrations also reported.

Chemical Concentration	50 ug/L	125 ug/L	250 ug/L	500 ug/L
INTESTINE				
40 day BCF	30	75	76	82
50 day BCF	30	77	85	82
60 day BCF	65	85	87	90
KIDNEY				
40 day BCF	28	18	19	20
50 day BCF	35	18	21	21
60 day BCF	40	18	30	28
LIVER				
40 day BCF	180	390	420	400
50 day BCF	200	400	420	550
60 day BCF	350	580	450	700

Significance

The statistical significance field is coded when the author has presented statistical analysis as compared to the controls in the test result.

The valid codes for this field are:

CODE	DEFINITION
SIG	Concentration(s) identified as significant (code lowest concentration in series of significant treatments)
ASIG	All toxicant concentrations significant (including single concentrations exposures)
NOSIG	Concentrations identified as not significant (code highest concentration in series of non-significant treatments)
ANOSIG	All toxicant concentrations not significant (including single concentrations exposures)
NA	Not applicable (use for LC50, EC50, BCF, MATC, NR-LETH, AND NR-ZERO)
NR	Not reported

If statistics are presented in the publication, unless the authors state otherwise, assume that the exposure treatments were compared to the controls.

P-value

Report the level of significance for the resulting endpoint value, as given by the author. Use operators (>,<,>=,<=) if given by the author. If statistical analysis has been performed, but the author(s) do not report a specific p-value for a given endpoint, record NR in the p-value field.

Method of Chemical Analysis

The M/U data field identifies whether nominal or quantified exposure dose values were reported by the author(s). For the specific exposure level, select from the dropdown menu whether toxicant concentration was measured (M) or calculated/nominal/unmeasured (U). When it is not clear whether reported concentrations are measured, calculated or unmeasured, select Not Reported (NR). This field defines the concentration which was used in reporting the endpoint. Publications may report the **Unmeasured** concentrations used in the Methods then report the endpoint concentration as **Measured**. **Measured** is selected in this case. Always select the code which represents whether the specific endpoint concentration was measured or unmeasured. If both measured and unmeasured concentrations for the specific effect/endpoint are reported, record only the measured concentrations. When chemical measurements are conducted on stock solutions, but nominal concentrations are reported for effects or endpoints, code as **Unmeasured**. When

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chemical measurements are conducted periodically throughout the exposure but the reported measurements are not correlated with the effects, code as **Unmeasured**. When chemical measurements are conducted periodically throughout the exposure and the effects are coordinated with the measurements, code as **Measured**.

Even if measured values are reported by the author to have deteriorated by the end of the exposure, the **Measured** code is still used. It is acceptable to assume that if the author used measured concentrations in residue analysis that these measured values were carried over to calculate BCF's. Endpoint Assignment

This field is used to identify the source of the effect or endpoint information. If the endpoint was reported by the author in the publication a 'P' is selected from the dropdown menu. Endpoints calculated by the author must be specifically identified (i.e., LD50, LT50 or NOEL/NOEC). If the endpoint was assigned by the reviewer, an 'R' is coded (i.e. NR-LETH, NOAEL, LOAEL).

Example 1. Author reports NOEC in paper but does not include companion endpoint - LOEC. If reviewer can determine LOEC from data, an '**R**' is coded for the LOEC (code 'by definition' in the EE REMARK field) and a '**P**' is coded for the NOEC.

Example 2. Author uses TLm (median tolerance limit) for 50% mortality endpoint. Reviewer can code the endpoint as LC50 and puts '**R**' for reviewer assigned endpoint (code TLM in the EE REMARK field).

Endpoint Comments (EFED)

In EFED reports, all text in this field is automatically transferred to the Comments field during the report download.

Include any comments related to the endpoint chosen. Comments may include text such as, "no clear dose response", "statistically significant increase over control", "statistically significant decrease over control", "fecundity and progeny effects also reported", "effect also reported in heart, kidneys, and thymus".

It is also used to record any Effect Measures under the same Effect Type of lesser or equal sensitivity to the reported endpoints. For example, if a population abundance (POP/ABND) LOAEL of 0.50 kg/ha and (POP/BMAS) biomass LOAEL of 0.75 kg/ha were both reported. The more sensitive LOAEL of 0.50 kg/ha would be reported as the endpoint and Biomass would be recorded in the Endpoint Comment field.

General Comments (EFED)

In EFED reports, all text in this field is automatically transferred to the Comments field during the report download.

The General Comments field is used to record information which may help differentiate between test results. For instance if two tests were performed under similar conditions

with the same species but one test was conducted in June and the other in September, then it would be appropriate to record June or September in the general comments field. This field is used to describe the controls used in an experiment, if multiple controls were reported. The General Comments field is used to describe mixtures of substrates used. All effect measurements that cannot be coded (due to no endpoints, no controls, etc.) are listed in the General Comments.

During the EFED report download, text from all comment fields (Experimental Design, Organism Comments, Chemical Comments, Duration Comments, Endpoint Comments, General Comments) are combined into the "Comments" field.

The following format is used in report download Comments field:

Organism comments	ORG/_____//
Exposure Duration comments	EXPDUR/_____//
Endpoint comments	EE/_____//
General comments	GENERAL/_____//
Chemical comments	CHAR/_____//
Experimental Design	EDES/_____//

Unify Media Characteristics

General Guidelines for Water Chemistry Parameters

These measured values pertain either to the test water chemistry or the dilution or culture water chemistry values. In the absence of test water chemistry parameters, it is acceptable to report the culture, holding tank, acclimation, control or dilution water, or pretest conditions (note in the General Comments where water chemistry parameters were taken, if not from test water). Water chemistry parameters measured prior to or after the exposure period are coded only if test water chemistries are not reported in the publication. If the author reports the test conditions as "similar" to other methods in the paper, do not code water chemistry values.

If in aquatic studies the values for these data fields are based on dilution water, reference water, or the author calculates these values prior to adding the test material, the value will be followed by an asterisk.

When water chemistries differ between samples (e.g., test chamber or water body), and results are obtained from only some of the samples, water chemistries should be reported for only those samples actually tested. The following are two examples on coding water chemistries:

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Conc	Temperature (Celsius)	pH
1 ug/l	20.4	7.9
	(20.1 - 20.7)	(7.5 - 8.3)
2 ug/l	20.5	8.0
	(20.2 - 20.8)	(7.6 - 8.4)
3 ug/l	20.4	7.8
	(20.0 - 20.8)	(7.7 - 7.9)

Example 1: Statistics are presented for Protein content and it is found to be significant at 2 ug/l. The data coded for Temperature and pH are for the specific concentration.

Code: Endpoint: LOAEL Effect: BCM Measurement: PRCO Concentration: 2 ug/l

pH: 8.0 Temperature: 20.5

Example 2: Statistics are presented for Glucose content and all concentrations are found to be not significant. The data coded for Temperature and pH are for the range of concentrations.

Code: Endpoint: NOAEL Effect: BCM Measurement: GLUC Concentration: 3 ug/l

pH: 7.5-8.4 Temperature: 20.0 - 20.8

When the author refers to the water chemistry values as approximate a "~" is coded in front of the value. Graphed data are coded as a range (e.g. 20 to 25) or as < or > values and the term "graphed" is noted in the General Comments field, e.g. temp/graphed//.

Water chemistry values should be coded as reported by the author.

Temperature

Report the temperature as presented by the author. Do not code temperatures for either aquatic or terrestrial studies noted as Room temperature. If a range of temperature is given, type "to" between the numbers (e.g. 15 to 25, not 15-25). Select from the unit dropdown menu either Celsius or Fahrenheit. Preferentially code the exposure temperature over the acclimation or pre-testing temperature

In aquatic studies, when temperatures are reported for incubation chambers or water baths, these temperatures are acceptable for reporting as test temperatures. Follow the general water chemistry parameter rules above for using asterisks in aquatic studies.

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In terrestrial studies, if the temperature of the treated media is not presented, but the temperature value is stated for the untreated or acclimation media, code the untreated media temperature and add an asterisk to the end of the value. When temperatures are reported for incubation chambers, these temperatures are acceptable for reporting as test temperatures.

Hardness/Units (EFED)

Report information about the test media hardness, as presented by the author. Enter the numeric value for hardness into the Hardness data field. Select the Hardness Units from the drop down list as reported by the author. Again make sure to use the word “to” instead of a dash between ranged values. Select the units from the dropdown menu. If the author only reports the terms “hard” or “soft”, report ‘NA’ in the Hardness Value field and select ‘HARD’ or ‘SOFT’ from the Units drop down menu. If the author reports a hardness value but does not identify a unit and/or refers to the value as “total”, standard units (mg / L CaCO₃) are assumed and the value coded.

Dissolved Oxygen

This parameter represents the dissolved oxygen of the media. Code the author-reported dissolved oxygen in this field. If a range of values is given, type “to” between the numbers. Choose the author-reported unit from the unit dropdown menu. If the author reports that the Dissolved Oxygen is saturated, report ‘NA’ in the Dissolved Oxygen Value field and select ‘SAT’ from the Units drop down menu.

Media pH (EFED)

Report the pH of the test media used, as reported by the author. If a range of pH is given, type “to” between the numbers (e.g. 5 to 7, not 5-7). For terrestrial studies, if the pH of the treated media is not presented, but the pH value is stated for the untreated or acclimation media, code the untreated media pH and add an asterisk to the end of the value. Follow the general water chemistry parameter rules above for using asterisks in aquatic studies.

Salinity

Report the salinity of the test media used, as reported by the author. If a range of salinity is given, type “to” between the numbers. Choose the appropriate unit from the dropdown menu.

Conductivity

This parameter represents the conductivity of the media. Code the author-reported

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conductivity in this field. If a range of values is given, type “to” between the numbers. Choose the author-reported unit from the unit dropdown menu.

Organic Matter/Units/Type (EFED)

Report information about the test media organic matter, as presented by the author. Enter the numeric value for organic matter into the Organic Matter Value data field. Sediment organic carbon values are not reported. Select the Organic Matter Type and Organic Matter Units from the drop down lists as reported by the author. Again make sure to use the word “to” instead of a dash between ranged values.

BLM Water Parameters

The following table lists water chemistry parameters for the Biotic Ligand Model. These parameters represent the water chemistry of the media. Input all author-reported parameters into their respective fields. If a range of values is given, type “to” between the numbers. Choose the author-reported unit from each of the unit dropdown menus.

Field Name	Definition	Comment
Alkalinity	Alkalinity	If the author reports an alkalinity value but does not identify a unit and/or refers to the value as “total”, standard units (mg / L CaCO ₃) are assumed and the value is coded.
Humic Acid	Humic Acid	
<u>Na</u>	Sodium	
<u>Cl</u>	Chlorine	
Dissolved inorganic carbon	Dissolved inorganic carbon	
<u>Ca</u>	Calcium	
<u>K</u>	Potassium	
<u>Mg</u>	Magnesium	
<u>SO4</u>	Sulfate	
<u>S</u>	Sulfur	

Reviewer QA Procedure

After a paper has been coded, it is forwarded to another experienced Reviewer for Quality Assurance. The QA procedure follows these general steps:

1. With paper in hand, the records are brought up in LITE Eval by inputting the EcoReferences Number the EcoRef Number search box on the References search screen. When the initial record list appears, look for missing reference information or species names.
2. Click on the Test or Result ID number and move between each of the screens or download the data to Excel for QA. Reviewers will have written test numbers (1, 2, 3, etc.) next to the endpoints coded in the paper that correspond to the test number they give each record. For each record, make sure you are following the information in the paper that corresponds to the endpoint coded.
3. First make sure that the chemical information on screen matches what is reported in the paper (CAS number, name, purity, grade, etc.)
4. Make sure that the species Latin name matches the test organism in the paper. The check to see that the organism Body Weight, Lifestage, and Age information is reported correctly. If cultivars or varieties are reported in the Organism Comments, be sure that they are correctly matched with the endpoints chosen from the paper.
5. Check that the correct Control has been coded.
6. Confirm the correct Number of Concentrations tested, the Concentration Values, and Units are the same as reported in the paper.
7. Check the paper and evaluate whether the reviewer coded the correct Concentration Type and Method of Chemical Analysis.
8. Quickly scan the water parameter fields (e.g. temperature, pH, Hardness) to see that they match the paper. Also quickly skim aquatic papers to make sure no water chemistry fields were missed in the coding.
9. If the paper is a field study, make sure the correct Field Study Information has been coded (e.g. Application Date, Substrate Code)
10. Closely examine the paper to be sure the correct Duration, Effect Measurement, and Response Site has been coded.
11. Check the endpoint coded and make sure the reviewer has chosen the correct Endpoint and corresponding Concentration and Conc Type.
12. Make sure the reported p-value is correct and that all Comment fields have reported the necessary information.

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13. Once all records have been QA'ed for a paper, skim the paper to make sure that no data is missing from coding, and that only the most sensitive endpoints for each Effect Measurement have been chosen.
14. If a small mistake is found the QA'er can simply make the change. However, when larger mistakes are found or when the QA'er disagrees with the durations or endpoints chosen, the QA'er should discuss the mistakes with the Reviewer and have them make the changes. When the QA'er and Reviewer cannot decide on the correct course of action, the issue is brought to the task manager. The task manager will either make a decision on how the endpoint should be coded or seek assistance from other experienced Reviewers.
15. When the QA'er deems the coding correct and complete they select the "RQAed" button to automatically approve all recently coded or modified records for a paper.
16. The paper is then sent for return memo processing.